

### **REMARKS**

The present Office Action addresses claims 1-7, 10-19, 21-27, 29-33, and 37, however claims 2-5, 13-16, and 25 are withdrawn from consideration. Remaining claims 1, 6, 7, 10-12, 17-19, 21-24, 26, 27, 29-33, and 35-37 stand rejected.

#### **I. Amendments to the Claims**

Applicants amend claim 36 to provide antecedent basis for the terms recess and cavity, as required by the Examiner. No new matter is added and entry of this amendment after final is proper, as the amendment eliminates the rejection pursuant to 35 U.S.C. §112, thereby placing the application in better condition for appeal.

#### **II. Summary of Claimed Subject Matter**

Independent claim 1 recites a spinal anchoring device having a bone-engaging member adapted to engage bone and having a head formed thereon, a spinal fixation element, and a U-shaped receiver member having a distal cavity that movably seats the head of the bone-engaging member and the U-shaped receiver member having a proximal recess that seats the spinal fixation element. The cavity and the recess include an opening extending therebetween and defined by the U-shaped receiver member. The opening has a size that allows a portion of the spinal fixation element to extend into the distal cavity but prevents passage therethrough of the spinal fixation element seated in the proximal recess. Claim 1 also recites a fastening element adapted to mate to the U-shaped receiver member to lock the spinal fixation element relative to the U-shaped receiver member while allowing the U-shaped receiver member to move freely relative to the bone-engaging member. This type of anchoring device is hereinafter generally referred to as a *non-locking polyaxial bone screw*.

Independent claim 12 recites a spinal anchoring system that includes a spinal fixation element, and a spinal anchoring device having a bone-engaging member with a head formed thereon and a U-shaped receiver member having a cavity that freely movably seats the head of the bone-engaging member in a distal portion of the cavity and that is configured to receive the spinal fixation element in a proximal portion of the cavity. The proximal and distal portions of the cavity are spaced apart by opposed protrusions defined by the U-shaped receiver member that allow a portion of a spinal fixation element to extend into the distal portion of the cavity but prevent contact between the bone-engaging member and the spinal fixation element. Claim 12 further recites a fastening element receivable within the U-shaped receiver member of the spinal anchoring device and being

configured, when mated to the U-shaped receiver member, to lock the spinal fixation element to the spinal anchoring device while allowing free movement of the U-shaped receiver member relative to the bone-engaging member.

Independent claim 24 recites a method for correcting spinal deformities that includes implanting a plurality of anchoring devices into adjacent vertebrae in a spinal column, each anchoring device including a bone-engaging member that is fixedly attached to the vertebra and a U-shaped receiver member having a distal cavity that seats a head formed on the bone-engaging member such that the U-shaped receiver member is freely movable relative to the bone-engaging member and the vertebra; coupling a spinal fixation element to a proximal recess in the U-shaped receiver member on each anchoring device such that the fixation element extends between each of the adjacent vertebrae, the cavity and the recess of the U-shaped receiver member including an opening extending therebetween and defined by the U-shaped receiver member, the opening further having a size that allows a portion of a spinal fixation element to extend into the cavity but prevents passage of the spinal fixation element therethrough; and locking the spinal fixation element to the U-shaped receiver member on each anchoring device to maintain the adjacent vertebrae at a fixed distance relative to one another, the spinal fixation element being seated in the opening but prevented from contacting the bone-engaging member, thereby allowing free movement of each U-shaped receiver member relative to each bone-engaging member.

Independent claim 32 recites a spinal anchoring device that includes a bone screw having a head and a shank, a spinal fixation element, a U-shaped receiver member having a distal seat for receiving at least a portion of the head of the bone screw, a proximal seat formed on an internal surface thereof that receives the spinal fixation rod, and opposed protrusions that define an opening between the distal seat and the proximal seat that allows a portion of the spinal fixation element to extend into the distal seat but that prevents passage therethrough of the spinal fixation element seated in the proximal seat, and a fastening element adapted to mate to the U-shaped receiver member to seat the spinal fixation rod in the proximal seat. The proximal seat is spaced a distance apart from the distal seat sufficient to allow polyaxial motion of the bone screw relative to the U-shaped receiver member upon seating of the spinal fixation rod in the proximal seat by the fastening element.

Independent claim 36 recites a spinal anchoring device having a bone-engaging member adapted to engage bone and having a head formed thereon, a U-shaped receiver member having a distal cavity that movably seats the head of the bone-engaging member and having a proximal recess

that is adapted to seat a spinal fixation element, the distal cavity and the proximal recess including an opening extending therebetween and having a size that prevents passage therethrough of a spinal fixation element seated in the proximal recess, and a fastening element adapted to mate to the U-shaped receiver member to lock a fixation element relative to the U-shaped receiver member while allowing the U-shaped receiver member to move freely relative to the bone-engaging member.

### **III. Argument**

#### **A. Rejection Pursuant to 35 U.S.C. §112, Second Paragraph**

The Examiner rejects claims 36 and 37 pursuant to 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner asserts that the limitations “the cavity” and “the recess” in claim 36 do not have sufficient antecedent basis. Applicant’s disagree, as lines 4 and 5 recite a “distal cavity” and a “proximal recess,” and thus the terms “the cavity” and “the recess” clearly refer to the “distal cavity” and the “proximal recess.” However, in order to eliminate any issues, Applicants amend claim 36 to recite “the distal cavity” and “the proximal recess,” thereby obviating the basis for this rejection.

#### **B. Rejection Pursuant to 35 U.S.C. §112, First Paragraph**

The Examiner rejects claims 12, 17-19, and 21-23 pursuant to 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement on the basis that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the invention. In particular, the Examiner asserts that the language in claim 12 reciting that the protrusions allow a spinal fixation element to extend into the *distal portion* of the cavity is unclear. Applicants disagree.

To satisfy the written description requirement of § 112, an applicant must convey with reasonable clarity to those skilled in the art that he or she was in possession of the claimed invention at the time of filing. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Literal support for the claimed invention is not required to satisfy the written description requirement. *E.g., Ex parte Parks*, 30 U.S.P.Q.2D 1234, 1236 (Bd. App. 1993) (“[a]dequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention”); *MPEP* § 2163.02 (“[t]he subject matter of the claim need not be described literally (i.e., using the same terms

or in haec verba) in order for the disclosure to satisfy the description requirement”); *MPEP* § 2173.05(i). Rather, the disclosure is sufficient if it would have conveyed to one having ordinary skill in the art that the applicant had possession of the *concept* of what is claimed. *Parks*, 30 U.S.P.Q.2D at 1236 (emphasis added). Applicant’s original disclosure clearly demonstrates possession of the claimed concept.

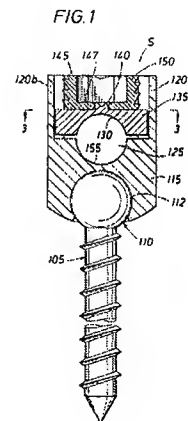
Claim 12 recites that the protrusions allow a portion of a spinal fixation element to extend into the distal portion of the cavity but prevent contact between the bone-engaging member and the spinal fixation element. This is clearly illustrated in FIG. 1D of the present application, which shows protrusions 22a and 22b formed in the U-shaped receiver head that allow a portion of the spinal rod 18 to extend into the distal cavity 20, but that prevent contact between the spinal rod 18 and the bone-engaging member, e.g., the head 14a of the bone screw. Accordingly, FIG. 1D clearly illustrates the claimed invention in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the invention. Possession of the claimed invention can be shown using figures or diagrams. *See, e.g., Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

**C. The Rejection Of Claims 1, 6, 7, 10-12, 17-19, 21-24, 26, 27, 29-33, and 35-37 Pursuant To 35 U.S.C. §103(a) Over Parker, Biedermann, And Schlapfer Should Be Reversed**

**1. The Examiner’s Rejection And The Scope and Content Of The Prior Art**

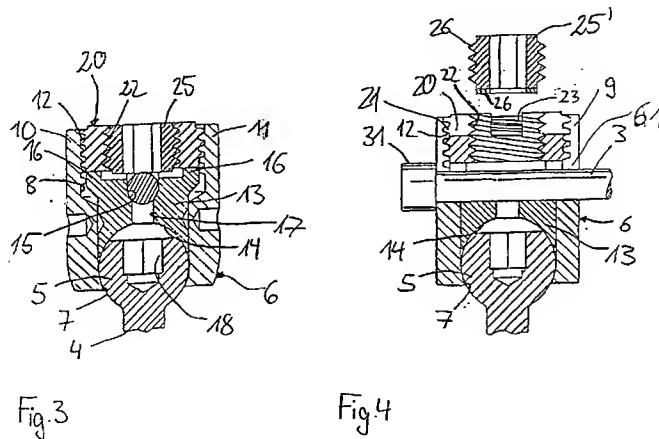
Claims 1, 6, 7, 10-12, 17-19, 21-24, 26, 27, 29-33, and 35-37 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Application No. 2004/0260284 (“Parker”) in view of U.S. Application No. 2004/0049190 (“Biedermann”) and further in view of U.S. Patent No. 6,063,090 of Schlapfer (“Schlapfer”).

The Examiner argues that Parker discloses a device having a bone-engaging member (105) with a spherical head (110) formed thereon, a U-shaped receiver member (115) having a proximal recess/seat (155) that receives a spinal rod (200) and a distal cavity (112) that seats the head of the bone-engaging member (105), and a threaded set screw/fastener to mate with the receiver to lock the spinal rod in position while allowing free polyaxial movement of the bone-engaging member (105), as shown in Figure 1 reproduced herein.



The Examiner admits that Parkers fails to each an opening extending between the proximal recess (155) and distal cavity (112) where the opening is sized to prevent passage of a spinal fixation element as well as the opening having a size that allows a portion of the spinal fixation element to extend into the distal cavity.

The Examiner relies on Biedermann to teach a passageway (17) too small to allow the spinal rod to pass but sufficient to allow a screw driver to engage the bone-engaging member, as shown in Figures 3 and 4 reproduced below.

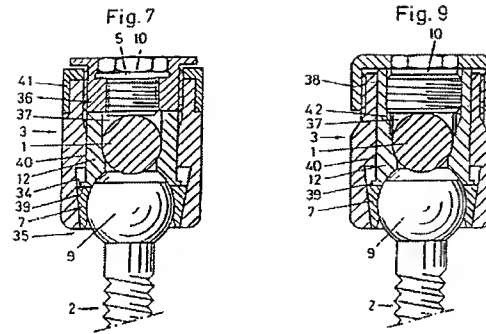


The Examiner argues that

[t]his allows the bone-engaging member to be pre-assembled to the U-shaped receiver member and ready to accept the spinal rod immediately after fixation in the bone without any intermediate steps thereby minimizing the complexity and duration of surgery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for a small passageway between the proximal recess and distal cavity of Parker in order to allow for the components to be pre-assembled thereby reducing surgical complexity and duration.

February 8, 2010 Office Action, p. 4.

The Examiner relies on Schlapfer to teach an arrangement such that the spinal rod (1) is partially seated within the distal cavity which houses a flat-topped (9) polyaxial screw (2), as shown in Figures 7 and 9 reproduced below.



The Examiner argues that

[i]t would have been obvious to one having ordinary skill in the art at the time of [the] invention to substitute a hole design of Schlapfer which allows the spinal rod to partially extend into the distal cavity and to substitute a fully-round headed polyaxial screw with a flat-topped polyaxial screw in order to provide an equivalent means of supporting a spinal rod on a polyaxial screw with predictable results.

*Id.* at pp. 3-4.

**2. *The Combination of Parker, Biedermann, and Schlapfer does not Render Obvious Claims 1, 6, 7, 10-11, 24, 26, 27, 29-31, and 36-37***

The Examiner's rejection should be reversed because Parker, in addition to the deficiencies admitted by the Examiner, further fails to teach a non-locking polyaxial bone screw, i.e., a device in which the spinal fixation element can be locked relative to the U-shaped receiver member while allowing the U-shaped receiver member to move freely relative to the bone-engaging member, as required by independent claims 1, 24, and 36. Moreover, even if it is assumed that Parker teaches a non-locking polyaxial bone screw, Biedermann does not remedy the deficiencies of Parker as Biedermann likewise fails to teach an opening defined by the receiver member. It also would not have been obvious to modify Parker to include an opening, as purportedly taught by Biedermann, and it would not have been obvious to modify Parker to include a flat-headed screw and to alter the screw such that the spinal fixation element extends into a distal cavity, as purportedly taught by Schlapfer.

**a. *Parker fails to teach a Non-Locking Polyaxial Bone Screw***

The Examiner relies on Figures 1 and 2 of Parker to teach a polyaxial bone screw that can receive and lock a spinal fixation element, i.e., rod (200), relative to the receiver head (115) while still allowing free movement of the receiver head (115) relative to a bone-engaging member, i.e.,

bone screw (105). Applicants disagree. The Examiner's interpretation is incorrect based on the teachings of Parker, and moreover cannot be applied because such an interpretation would result in Parker's device being not enabled.

At the outset, while a claimed invention may be anticipated or rendered obvious by a drawing in a reference regardless of whether the drawing disclosure was accidental or intentional, a drawing is only available as a reference for all that it teaches a person of ordinary skill in the art. See *In re Meng*, 492 F.2d 843 (C.C.P.A. 1974). The drawings must be evaluated for what they reasonable suggest to a person having ordinary skill in the art. See *In re Wagner*, 20 C.C.P.A. 985, 987 (C.C.P.A. 1933). Here, Parker does not reasonably suggest a non-locking polyaxial bone screw. Figures 1 and 2 of Parker appear to be a generic illustration that lacks detail with respect to the distal portion of the receiver head, as this portion of the receiver is not of relevance to the claimed invention. While the drawings are unclear, the specification of Parker suggests a construct in which the entire assembly is locked to prevent movement of both the rod and the receiver head relative to the bone screw.

In particular, in the Background of the Invention section, Parker describes a typical pedicle screw, explaining that

[t]he screw shank typically extends through the bottom of the screw head and is held in place in a polyaxial joint that allows for flexibility to adapt to the desired position of the vertebra. The closure cap is then typically inserted down on top of the rod and threaded into the receiver or head, locking the rod down tightly to the receiver as well as locking down the polyaxial joint between the receiver and the screw shank.

Parker at para. [0004] (emphasis added). Parker thus makes it clear that *typical* pedicle screws lock the entire construct, including locking the receiver head relative to the bone screw. While the Background section is directed to prior art constructs, as noted by the Examiner at pg. 5 of the Office Action dated February 8, 2010, Parker makes it clear that the invention improves upon the *typical* pedicle screw by providing an anti-splaying feature located in the proximal portion of the receiver head. Parker does not teach or even suggest any configuration in which the receiver head remains free to move relative to the bone screw after the rod is locked within the receiver head. In fact, as admitted by the Examiner, "Parker is silent to the screw being locked in combination with the rod

and the receiver.” *Id.* For reasons explained below, such silence does not reasonably suggest a non-locking polyaxial bone screw, as required by the claimed invention.

Parker states that “FIG. 6 illustrates the use of pedicle screws S with a common rod 200 locking multiple vertebra in a desired alignment.” If the pedicle screw S is interpreted to have a non-locking polyaxial bone screw, as asserted by the Examiner, then the screw could not lock multiple vertebra in a desired alignment as required by Parker. Accordingly, the teachings of Parker do not reasonably suggest a non-locking polyaxial bone screw, but instead suggest a construct that fully locks to prevent movement of the rod relative to the receiver head as well as movement of the receiver head relative to the bone screw. The figures merely fail to illustrate the details of this feature, as it is not relevant to the primary purpose of the invention (i.e., to prevent splaying).

The teachings also reasonably suggest that, while not shown, Parker’s pedicle screw includes an insert between the rod and the head of the bone screw that compresses to lock the receiver head relative to the rod. Parker explains that the “polyaxial head 115 includes a floating saddle 112 where the polyaxial screw head 110 articulates, giving the polyaxial screw shank 105 polyaxial capability.” Parker at para. 0019 (emphasis added). Reference 112, however, merely points to the spherical cavity that seats the screw head. It is thus unclear what is meant by the term “floating saddle.” However, Parker continues on to state that “[t]he receiver 115 may contain features to allow for mechanical assistance in seating the rod into the receiver 115. These features are well known in the art and will not be further discussed.” *Id.* These mechanical features well known in the art include inserts or saddles that sit on top of the screw head and seat the rod to allow the insert or saddle to be compressed by the rod thereby locking the screw head relative to the receiver. Biedermann and Schlapfer, relied on by the Examiner, both teach such inserts or saddles. It is thus believed that Figure 1 of Parker fails to include the details of the insert or saddle because such features are “well known in the art” and because the primary object of the invention is directed to the anti-splaying feature located in the upper portion of the receiver.

Accordingly, a person skilled in the art would not interpret Parker as teaching a pedicle screw having a non-locking polyaxial bone screw. Rather, they would interpret Figure 1 as simply lacking the details of the insert or saddle mentioned in the specification.



*b. Parker Is Not Enabled If The Examiner's Interpretation Is Applied*

Parker further reasonably suggests that the pedicle screw includes an insert because Parker's screw would not be enabled without an insert.

To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate. "A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). See *Bristol-Myers Squibb v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 1374, 58 USPQ2d 1508, 1512 (Fed. Cir. 2001) ("To anticipate the reference must also enable one of skill in the art to make and use the claimed invention."); *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996) ("To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.").

*Elan Pharms., Inc. v. Mayo Found.*, 346 F.3d 1051, 1054 (Fed. Cir. 2003). Parker's construct is not enabled if Figure 1 is interpreted as disclosing a non-locking polyaxial bone screw because without an insert, the device cannot be assembled. As shown in Figure 1, the head (110) of the bone screw sits within a spherical cavity. While Figure 1 illustrates a cross-sectional view, as partially shown in Figure 2 the receiver head includes a circular opening in the distal-most end thereof that leads into the spherical cavity. The circular opening is non-expandable due to its circular shape, and it necessarily must have a diameter that is less than a diameter of the head of the bone screw in order to retain the head therein. As such, the head of the bone screw cannot be inserted through the circular opening, i.e., bottom-loaded. This presents a problem that renders the device inoperable. If the receiver head truly lacks an insert as illustrated in Figure 1, then the bone screw cannot be accessed through the receiver head to drive the screw into bone using a drive slot, as disclosed by Parker in paragraph [0018]. Thus, the bone screw would have to be driven into bone *prior* to attaching the receiver head to the bone screw. However, since the bone screw cannot be bottom-loaded into the cavity in the receiver head, the device cannot be assembled. The circular opening at the bottom of the receiver head would simply prevent passage of the screw head therethrough. Thus, while an opening and insert are not illustrated in the drawings of Parker, the only possible way to seat the head of Parker's screw within the circular cavity would be to insert the shank of the bone screw through the proximal end of the receiver and through an opening in the portion of the receiver that separates the rod-seating cavity from the spherical cavity that seats the head of the bone screw. Since the proximal opening

would have to have a diameter that is larger than a diameter of the head of the bone screw to allow the head to pass therethrough and be seated within the distal spherical cavity, an insert or saddle would need to be inserted into the receiver head and seated on top of the head of the bone screw to retain the receiver head on the bone screw. The saddle or insert is also needed to provide the structure that is illustrated, albeit without the necessary details.

In response to Applicants arguments that Parker is not enabled, the Examiner admits that “Parker discloses the possibility of an insert ‘floating saddle,’” but the Examiner argues that Parker does not require one to function as intended. Office Action mailed Feb. 8, 2010, p. 8. As explained above, if Parker truly lacks an insert, that the device cannot function as intended because there would be no way to implant the screw into bone.

Accordingly, Parker cannot reasonably be interpreted as teaching a non-locking polyaxial bone screw construct, as required by independent claims 1, 24, and 36. To the contrary, the specification suggests a construct having an insert or saddle that locks the bone screw relative to the receiver when the rod is locked within the receiver. Parker’s device is also not enabled under the Examiner’s interpretation, thus further precluding such an interpretation of Figure 1 of Parker.

*c. Biedermann Fails To Remedy The Deficiencies Of Parker*

As noted above, Parker is the primary reference in the obviousness rejection, however the Examiner concedes that Parker lacks the opening of claims 1, 24, and 36 and argues that it would have been obvious to modify Parker to include such an opening using the teachings of Biedermann.

Biedermann, however, is equally deficient, as Biedermann lacks an opening *defined by* a U-shaped receiver member. While it is true that Biedermann discloses a central bore (17), the central bore (17) is defined by a pressure element (13), not by the receiver part (6) as required by claims 1, 24, and 36. *See* Biedermann at FIG. 3. Thus, if one were to combine Parker and Biedermann, they would simply add a pressure element (i.e., an insert), not just an opening, to Parker. Such a combination would not result in the claimed invention because an insert will necessarily lock the screw head relative to the receiver.

d. *Schlapfer Fails To Remedy The Deficiencies Of Parker and Biedermann*

As discussed above, the Examiner further admits that Parker as modified in view of Biedermann fails to teach an opening having a size that allows a portion of a spinal fixation element to extend into the distal cavity but that prevents passage therethrough of the spinal fixation element seated in the proximal recess, as further required by claims 1, 24, and 36. The Examiner relies on Schlapfer to remedy this deficiency of Parker and Biedermann, arguing that it would have been obvious to further modify Parker in view of Biedermann to lower the rod such that it is positioned within the distal cavity, and to make the screw head flat (which is required to make room for the rod) “in order to provide an equivalent means of supporting a spinal rod on a polyaxial screw with predictable results.”

Schlapfer does not remedy the deficiencies of Parker and Biedermann as Schlapfer does not teach an opening that allows a rod to be positioned within a distal cavity. The claimed opening extends between the proximal recess and the distal cavity. In Schlapfer, the opening extends through an insert 12, shown in Figures 6 and 7, and thus the proximal recess is located proximal of the insert and the distal cavity is located distal of the insert. As is clearly shown in Figure 7 of Schlapfer, the rod 1 is fully disposed within the insert 12 and does not extend beyond the distal end of the insert, i.e., the distal end of the opening. The rod therefore does not extend into the distal cavity.

Accordingly, none of the references teach or even suggest an opening having a size that allows a portion of a spinal fixation element to extend into the distal cavity.

e. *It Would Not Have Been Obvious To Modify Parker To Position the Rod Within the Distal Cavity*

Even if Schlapfer could be relied on to remedy the deficiencies of Parker in view of Biedermann, it would not have been obvious to make such a modification. Schlapfer does not have any teachings relating to the position of the rod or any advantages thereof that would motivate a person having ordinary skill in the art to make the modification proposed by the Examiner. Schlapfer merely illustrates a rod that has a portion that the Examiner argues extends into the distal cavity, but Schlapfer does not even mention the illustrated location of the rod or any advantages of such positioning. The only reason Schlapfer has an opening is because, like Biedermann, Schlapfer has an insert that seats the spinal rod. The insert is sized to provide the proper compression on the screw head to lock both the rod and the screw head relative to the receiver head. If a person having

ordinary skill in the art were to modify Parker in view of the teachings of Schlapfer, they would simply add an *insert* that seats a rod as positioned, and not merely an opening. Such a modification would not result in the claimed invention.

More importantly, even if Parker's receiver head is modified to have an enlarged opening, as suggested by the Examiner, such a modification would not result in the rod extending into the distal cavity. The size of an opening is irrelevant to the location of the rod. An opening formed in Parker would merely be an enclosed *circular* opening in the receiver head that the rod extends across. Such an enclosed circular opening would not allow any portion of an elongate rod extending across the opening to extend into the distal cavity. The only way the rod would extend into the distal cavity in Parker would be if the depth of the U-shaped cut-outs in the sidewalls of the receiver head were increased and extended into the opening to form cut-outs in the opening that would allow the rod to extend through the receiver head at a position that is below the location of the opening. There is no teaching in any reference cited by the Examiner to make such a modification, and thus even if Parker, Biedermann, and Schlapfer could be combined, the combination would not result in the claimed invention.

Accordingly, the combination of references fails to teach or even suggest the claimed invention, and therefore independent claims 1, 24, and 36, as well as claims 6, 7, 10-11, 26, 27, 29-31, and 37 which depend therefrom, therefore distinguish over the prior art and represent allowable subject matter.

**3. *The Combination of Parker, Biedermann, and Schlapfer does not Render Obvious Claims 12, 17-19, 21-23, 32-33 and 35***

Independent claims 12 and 32 are somewhat similar to claims 1 and 24 in that claims 12 and 32 require a non-locking polyaxial screw. Claims 12 and 32 are also similar to claims 1 and 12 in that they require that a portion of the spinal fixation element extend into the distal portion of the cavity (claim 12) or a distal seat (claim 32) that seats the head of the bone-engaging member. Accordingly, for all of the same reasons discussed above with respect to claims 1 and 24, claims 12 and 32 distinguish over Parker, Biedermann, and Schlapfer and represent allowable subject matter.

Claims 12 and 32 further distinguish over the cited prior art because claims 12 and 32, unlike claims 1 and 24, recite that the proximal and distal portions of the cavity in the U-shaped receiver member (claim 12) or the proximal and distal seats (claim 32) are spaced apart by *opposed*

*protrusions*. None of the cited references teach or even suggest opposed protrusions that separate proximal and distal portions of a cavity (claim 12) or proximal and distal seats (claim 32).

According to the Examiner's interpretation, Parker does not have any opening that separates the cavity in the receiver head into proximal in distal portions, and thus necessarily lacks the claimed opposed protrusions. Biedermann and Schlapfer each have an opening, albeit formed in an insert and not defined by the U-shaped receiver member. Regardless, Biedermann and Schlapfer both lack the claimed *opposed protrusions*. The openings in the inserts of Biedermann and Parker are entirely circular in shape and thus could only be considered as forming a single protrusion. Beidermann and Parker simply lack anything that can be considered to be *opposed* protrusions.


Claims 12 and 32, as well as claims 17-19, 21-23, 33, and 35 which depend therefrom, therefore distinguish over Parker, Biedermann, and Schlapfer and represents allowable subject matter.

### ***Conclusion***

Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Dated: March 9, 2010

Respectfully submitted,

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